

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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NEW YORK STATE RESTAURANT ASSOCIATION,

Plaintiff,
-against- 07 Civ. 5710 (RJH)

NEW YORK CITY BOARD OF HEALTH, NEW YORK
CITY DEPARTMENT OF HEALTH AND MENTAL
HYGIENE, and THOMAS R. FRIEDEN, In His Official
Capacity as Commissioner of the New York City
Department of Health and Mental Hygiene,

Defendants.

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**DEFENDANTS' MEMORANDUM OF LAW IN OPPOSITION TO PLAINTIFF'S
MOTION FOR DECLARATORY AND PRELIMINARY INJUNCTIVE RELIEF**

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TABLE OF CONTENTS

PRELIMINARY STATEMENT.....	1
ARGUMENT.....	4
I. THE NLEA DOES NOT PREEMPT A STATE OR LOCAL GOVERNMENT FROM REQUIRING RESTAURANTS TO POST CALORIES ON MENUS.....	4
a. PLAINTIFF MUST OVERCOME A PRESUMPTION AGAINST PREEMPTION WHEN IT CHALLENGES A REGULATION INVOLVING THE HISTORIC POLICE POWERS OF STATE AND LOCAL GOVERNMENTS.....	4
b. A STATE OR LOCAL GOVERNMENT REGULATION CANNOT BE IMPLIEDLY PREEMPTED BY THE NLEA.....	5
c. RATHER THAN PREEMPT, THE NLEA EXPRESSLY RECOGNIZES THE RIGHTS OF STATE AND LOCAL GOVERNMENTS TO REQUIRE RESTAURANTS TO DISCLOSE NUTRIENT INFORMATION SUCH AS CALORIES.....	6
d. THE DISCLOSURE OF A NUTRITIONAL FACT IS NOT THE MAKING OF A NUTRIENT CONTENT CLAIM.....	8
e. ASSUMING ARGUENDO THAT PURELY FACTUAL STATEMENTS ABOUT CALORIE VALUES ARE GOVERNED BY 21 U.S.C. § 343(r), THE NYSRA STILL CANNOT CLEARLY ESTABLISH THAT THE NLEA PREEMPTS HEALTH CODE 81.50.....	11
II. NYSRA’S REQUEST FOR PRELIMINARY INJUNCTIVE RELIEF ON ITS FIRST AMENDMENT CLAIM SHOULD BE DENIED SINCE IT HAS NOT DEMONSTRATED A LIKELIHOOD OF SUCCESS ON THIS CLAIM.....	17
a. THE PROPER ANALYTICAL FRAMEWORK FOR JUDGING COMPELLED FACTUAL DISCLOSURE IS THE <u>ZAUDERER</u> REASONABLENESS STANDARD.....	17
b. HEALTH CODE 81.50 IS RATIONALLY RELATED TO THE CITY'S LEGITIMATE INTEREST IN PROTECTING PUBLIC HEALTH.....	22
c. HEALTH CODE 81.50 DOES NOT UNLAWFULLY CHILL PROTECTED SPEECH.....	27
CONCLUSION.....	30

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**DEFENDANTS' MEMORANDUM OF LAW IN
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Defendants the New York City Board of Health ("Board of Health"), the New York City Department of Health and Mental Hygiene ("DOH"), and Thomas R. Frieden, in his official capacity as Commissioner of DOH (collectively the "City"), by their attorney, Michael A. Cardozo, Corporation Counsel of the City of New York, submit this memorandum of law in opposition to plaintiff's motion for declaratory relief on its preemption claim and for preliminary injunctive relief on its First Amendment claim.

PRELIMINARY STATEMENT

There is an obesity epidemic that threatens the health of New Yorkers. This epidemic correlates with a change in people's eating habits. New Yorkers now are consuming more meals -- and more calories -- at restaurants, where food is exempt from the mandatory nutritional disclosure requirements of the National Labeling and Education Act of 1990 ("NLEA"). The effects of this epidemic on New Yorkers and New York City, and the correlation between obesity and calorie intake are explained in detail in the accompanying

declaration of DOH Commissioner Thomas R. Frieden, M.D., M.P.H. at ¶¶ 3, 4, 6, 9, 14, 15, 19, 20 (“Frieden Decl.”).

Restaurants in the City are subject to the requirements enacted by the Board of Health and codified in the New York City Health Code (“Health Code”); these requirements are enforced by DOH.¹ To combat the obesity epidemic, in December 2006 the Board of Health enacted Health Code section 81.50 (“Health Code 81.50”).² Effective July 1, 2007, it requires restaurants that have ascertained and made public the calorie values for standardized menu items to post those values on menus and menu boards (collectively “menus”), where they will be readily available to consumers making food choices.

This lawsuit stems from the unwillingness of restaurants to comply with this important public health provision, even though these restaurants already make calorie information available elsewhere. Plaintiff New York State Restaurant Association (“NYSRA”) seeks to block implementation of this law, and ironically seeks shelter under the NLEA. The NYSRA contends that since one section of the NLEA regulates restaurants’ voluntary claims that characterize the nutrient content (e.g. “low calorie”) of their food, it preempts state and local governments from requiring restaurants (consistent with their traditional police power to regulate restaurants within their borders) to disclose purely factual information about their food. This argument, however, blurs the distinction between nutrient content claims, and the mandated disclosure of nutritional facts, like calorie amounts, which is addressed in a completely separate section. Because in that latter section the NLEA permits states to mandate that restaurants

¹ The New York City Charter sets forth the powers of the Board of Health and DOH. See Charter §§ 551-568.

² The process that led to the adoption of Health Code 81.50 is set forth in the Frieden Decl. ¶¶ 4-5.

disclose nutritional facts, the NLEA does not preempt a regulation like Health Code 81.50 that requires restaurants to post calories on menus. Accordingly, the NYSRA's request for declaratory relief on its preemption claim should be denied since it has not established that Health Code 81.50 should be preempted.³

The NYSRA also argues that Health Code 81.50 compels commercial speech and thus violates the First Amendment. For a regulation like this one, that compels the disclosure of only factual information, the appropriate test to use when assessing its constitutionality is Zauderer v. Office of Disciplinary Counsel, 471 U.S. 626 (1985), which merely requires that the disclosure be reasonably related to the state's interest in enacting the regulation. Because the requirement that restaurants post calories on menus is reasonably related to the City's effort to reduce obesity, it is constitutionally permissible. Accordingly, the NYSRA's request for a preliminary injunction on its First Amendment claim should also be denied since the NYSRA has not established a likelihood of success.

³ The NYSRA has not requested a preliminary injunction on its preemption claim; any such request would have to be denied in any event since the NYSRA can establish neither a likelihood of success on the merits nor irreparable harm.

ARGUMENT

I. THE NLEA DOES NOT PREEMPT A STATE OR LOCAL GOVERNMENT FROM REQUIRING RESTAURANTS TO POST CALORIES ON MENUS.

A. PLAINTIFF MUST OVERCOME A PRESUMPTION AGAINST PREEMPTION WHEN IT CHALLENGES A REGULATION INVOLVING THE HISTORIC POLICE POWERS OF STATE AND LOCAL GOVERNMENTS.

“Identifying congressional purpose is the ‘ultimate touchstone’ of a preemption inquiry.” New York State Pesticide Coalition, Inc. v. Jorling, 874 F.2d 115, 119 (2d Cir. 1989) (quoting Malone v. White Motor Corp., 435 U.S. 497, 504 (1978)). While preemption “fundamentally is a question of congressional intent,” English v. General Elec. Co., 496 U.S. 72, 79 (1990) (citation omitted), there is a presumption against federal preemption when Congress passes legislation in a field, such as here,⁴ traditionally reserved to the states.⁵ Medtronic, Inc. v. Lohr, 518 U.S. 470, 485 (1996); Bates v. Dow Agrosciences LLC, 544 U.S. 431, 449 (2005) (“we assume that a federal statute has not supplanted state law unless Congress has made such an intention clear and manifest” (internal quotations and citations omitted)). See also Pelman v. McDonald’s Corp., 237 F. Supp. 2d 512, 526 (S.D.N.Y. 2003) (Sweet, J.) (finding no

⁴ For “the purposes of the Supremacy Clause, the constitutionality of local ordinances is analyzed in the same way as that of statewide laws.” Hillsborough County v. Automated Medical Labs., 471 U.S. 707, 713 (1985).

⁵ The power to regulate restaurants is a State power. See Sligh v. Kirkwood, 237 U.S. 52, 59 (1915) (“The power of the state to prescribe regulations which shall prevent the production within its borders of impure foods, unfit for use, and such articles as would spread disease and pestilence, is well established.”); Grocery Mfrs. of America v. Gerace, 755 F.2d 993, 1003 (2d Cir.), cert. denied, 106 S. Ct. 69 (1985) (“States have traditionally acted to protect consumers by regulating foods produced and/or marketed within their borders”). The U.S. Food and Drug Administration (“FDA”) also recognizes the authority of local government in the area of foodservice establishments. See, e.g., Draft Voluntary Hazard Analysis and Critical Control Point Manuals, 70 Fed. Reg. 42072 (July 21, 2005) (“While the responsibility for regulating retail and foodservice establishments lies primarily with State, local, and tribal jurisdictions, FDA provides assistance to these jurisdictions through multiple means....” (emphasis added)).

preemption under 21 U.S.C. § 343-1(a)(4), and noting that “the historic police powers of the States [are] not to be superseded by ... Federal Act unless that [is] the clear and manifest purpose of Congress” (quoting Cipollone v. Liggett Group, Inc., 505 U.S. 504, 516 (1992))). In fact, the “presumption against federal pre-emption of a state statute designed to foster public health ... has special force when it appears ... that the two governments are pursuing common purposes.” Pharm. Research & Mfrs. of Am. v. Walsh, 538 U.S. 644, 666 (2003) (citations omitted). Given the state and local governments’ historic police powers, even a “plausible” reading favoring preemption should be rejected since “we would nevertheless have a duty to accept the reading [of the statute] that disfavors preemption.” Bates, 544 U.S. at 449.

B. A STATE OR LOCAL GOVERNMENT REGULATION CANNOT BE IMPLIEDLY PREEMPTED BY THE NLEA.

The NYSRA argues that the NLEA, Pub. L. No. 101-535, both expressly and impliedly, preempts Health Code 81.50. The only form of preemption this Court need consider is express preemption since there is no implied preemption pursuant to NLEA section 6(c), which provides that the NLEA “shall not be construed to preempt any provision of State law, unless such provision is expressly preempted under [21 U.S.C. § 343-1].” 21 U.S.C. § 343-1, note. See also Pub. L. No. 101-535, 104 Stat. 2353, 2364. Since Congress clearly articulated that the NLEA is not to be the basis for an implied preemption claim, English, 496 U.S. at 79 (“when Congress has made its intent known through explicit statutory language, the Court’s task is an easy one”), plaintiff must demonstrate that Congress expressly preempted states and local governments from enacting calorie posting requirements like Health Code 81.50.⁶

⁶ Moreover, there is “an inference that an express pre-emption clause forecloses implied pre-emption.” Freightliner Corp. v. Myrick, 514 U.S. 280, 289 (1995). And the NYSRA would bear a heavy burden of demonstrating that the NLEA implicitly preempts Health Code 81.50. See Hillsborough County, 471 U.S. at 716. Contrary to NYSRA’s contention, Health Code 81.50 is not implicitly preempted since it does not stand “as an obstacle to the accomplishment

C. RATHER THAN PREEMPT, THE NLEA EXPRESSLY RECOGNIZES THE RIGHTS OF STATE AND LOCAL GOVERNMENTS TO REQUIRE RESTAURANTS TO DISCLOSE NUTRIENT INFORMATION SUCH AS CALORIES.

The NLEA amended the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301, et seq. (“FDCA”) by the enactment of 21 U.S.C. §§ 343(q) & (r). The two purposes of the NLEA legislation, as voiced by Congressman Waxman, are to “give consumers nutrition information about the products they are consuming; and, second, prohibit misleading [nutrient content claims and] health claims.” 136 Cong. Rec. H5843 (July 30, 1990).

As to the NLEA’s first purpose, 21 U.S.C. § 343(q) requires certain nutritional facts, including calorie information, to be disclosed on the label or labeling of food intended for human consumption, such as that sold in supermarkets. 21 U.S.C. § 343(q)(1). Restaurants, however, are exempt from this requirement and thus under the NLEA need not disclose how many calories are in the foods they serve. 21 U.S.C. §§ 343(q)(1) & (5)(A)(i).

21 U.S.C. § 343(r), on the other hand, regulates claims voluntarily made by purveyors of food on labels or labeling that either “characterizes the level of any nutrient” (known as nutrient content claims) or “characterizes the relationship of any nutrient ... to a disease or health-related condition” (known as health claims). With limited exceptions, when

and execution of the full purposes and objectives of Congress.” Id. at 713 (quoting Hines v. Davidowitz, 312 U.S. 52, 67 (1941)). Indeed, the NLEA and Health Code 81.50 pursue common purposes. Pharm. Research, 538 U.S. at 666. The purpose of the NLEA was to “make available nutrition information that can assist consumers in selecting foods that can lead to healthier diets.” Public Citizen, Inc. v. Shalala, 932 F. Supp. 13, 14 (D.D.C. 1996) (quoting Final Rule, 58 Fed. Reg. 2066, 2302 (Jan. 6, 1993)). Similarly, the Board of Health, in the Statement of Basis and Purpose contained within the Notice of Adoption of Health Code 81.50, noted: “When consumers are made aware of nutrition information at the point of purchase, disease risk perceptions increase, attitudes toward the products change, and purchasing intentions for unhealthy products decrease.” Frieden Decl., Ex. 10, at 2. Similarly, the Statement of Basis and Purpose noted that providing “simple, point-of-purchase calorie information would allow consumers to make more informed food choices in restaurants, just as they currently can in supermarkets.” Id. at 3.

making such nutrient content⁷ or health claims, the purveyors must use terms defined by the FDA. 21 U.S.C. § 343(r)(2)(A)(i).

The NLEA's express preemption provisions are set forth at 21 U.S.C. § 343-1(a), and its fourth paragraph, section 343a-1(a)(4) applies to nutritional labeling requirements. Significantly, it is limited and does not preempt all state and local regulations. Rather, section 343-1(a)(4) preempts "any requirement for nutrition labeling of food ... except a requirement for nutrition labeling of food which is exempt under subclause (i) ... of [21 U.S.C. § 343(q)(5)(A) [i.e. food served in restaurants]]." (emphasis added). In other words, when enacting the NLEA, Congress specifically chose not to preempt state and local regulations that require restaurants to disclose nutritional information for the food they serve.

Since "the plain wording of [a preemption provision] necessarily contains the best evidence of Congress' pre-emptive intent," CSX Transp., Inc. v. Easterwood, 507 U.S. 658, 664 (1993), the NLEA must be read as preserving the rights of state and local governments to enact regulations like Health Code 81.50 that requires restaurants to disclose how many calories are in the food they serve. See Pelman, 237 F. Supp. 2d at 526 (restaurant food is not preempted under 21 U.S.C. § 343-1(a)(4)).

⁷ A November 2006 memorandum to the Board of Health by a DOH non-lawyer inaccurately stated that calorie posting constituted a nutrient content claim while summarizing numerous comments on the calorie posting proposal. NYSRA App., Ex. L, at 11.

D. THE DISCLOSURE OF A NUTRITIONAL FACT IS NOT THE MAKING OF A NUTRIENT CONTENT CLAIM.

Attempting to escape from the clear language of sections 343(q) and 343-1(a)(4), the NYSRA asserts that if restaurants merely provide calorie values they nonetheless are making nutrient content claims and subjecting themselves to section 343(r) and its preemption provision, 21 U.S.C. § 343-1(a)(5). This attempt fails.

One does not make a nutrient content claim merely by disclosing, voluntarily or otherwise, the number of calories that are contained in an item of food. That fact is defined by statute as nutritional information. 21 U.S.C. § 343(q)(1)(C). In contrast, a nutrient content claim must somehow characterize the level of calories in the food item it is describing. See 21 U.S.C. § 343(r)(1)(A). In other words, a nutrient content claim (e.g. “low calorie”) is a statement made in reference to a nutrient level, but not a statement as to the nutrient level itself. See, e.g., 21 U.S.C. §§ 343(r)(2)(G)(i) & (ii).

Section 343(r) was intended to address misleading or unsubstantiated nutrient content or health claims.⁸ “This provision states that a food is misbranded if it bears a claim in its label or labeling that either expressly or implicitly characterizes[⁹] the level of any nutrient of the type required to be declared as part of nutrition labeling, unless such claim has been specifically defined (or otherwise exempted) by regulation.” Food Labeling: Nutrient Content Claims, 56 Fed. Reg. 60421 (Nov. 27, 1991) (emphasis added).

⁸ See 136 Cong. Rec. H5836, H5840 (Congressman Waxman notes that the bill would require “terms such as ‘light’ to have a single meaning”).

⁹ A phrase like “low calorie” would be an example of an express claim, and a phrase like “lite” (which implies that the food is low in some nutrient) would be an example of an implied claim. H.R. Rep. No. 101-538, at 19 (1990), reprinted in 1990 U.S.C.C.A.N. 3336, 3349.

Posting calorie values on a website or in a leaflet (as some NYSRA members do)¹⁰ or on a menu in compliance with Health Code 81.50, is not equivalent to making a nutrient content claim about those values. The FDA regulations recognize this: the “labeling of a product may contain a statement about the amount ... of a nutrient if: ... (3) The Statement does not in any way implicitly characterize the level of the nutrient in the food and it is not false or misleading in any respect (e.g. ‘100 calories’ or ‘5 grams of fat’).” 21 C.F.R. § 101.13(i). In contrast to the regulation repeatedly relied on by the NYSRA,¹¹ this provision directly addresses the precise requirement mandated by Health Code 81.50 (the number of calories), and specifically provides that such a requirement does not “characterize” a nutrient level.¹²

When asked to consider the nature of nutrient content claims, the FDA has repeatedly reached the same conclusion: “FDA finds that there are some circumstances in which an amount claim cannot be considered to characterize in any way the level of a nutrient in a food. For example, the statement ‘100 calories’ or ‘5 grams of fat’ on the principal display panel of a food would be a simple statement of amount that, by itself, conveys no implied characterization

¹⁰ Exhibits to declarations filed in support of the NYSRA’s motion indicate that certain NYSRA restaurants identify calorie amounts in a straight forward factual recitation. See Demuth Decl. Ex. D (McDonald’s); Haugen Decl. Ex. A (Burger King); Richardson Decl. Ex. A (White Castle); Burnett Decl. Ex. A (Cold Stone); Liewen Decl. Exs. A (Pizza Hut), B (KFC), C (Taco Bell); LeClair Decl. Ex. A (Dunkin Donuts).

¹¹ The NYSRA contends that an FDA regulation supports its argument that identifying the amount of calories on a menu is a nutrient content claim. This provision provides: “A claim that expressly or implicitly characterizes the level of a nutrient”, and then continues “(1) [a]n expressed nutrient content claim is any direct statement about the level (or range) of a nutrient in the food, e.g., ‘low sodium’ or ‘contains 100 calories.’” 21 C.F.R. § 101.13(b). In fact, this provision indicates that a section 343(r) nutrient content claim is one that uses descriptive words, such as “contains.”

¹² Moreover, the FDA has a specific regulation pertaining to calorie claims. See 21 C.F.R. § 101.60 (“Nutrient content claims for the calorie content of foods”). It defines specific terms that must be used when making nutrient content claims and provides additional evidence that mere recitals of calorie values are not such claims.

of the level of the nutrient.” Food Labeling: Nutrient Content Claims, 58 Fed. Reg. 2302, 2310 (Jan. 6, 1993) (emphasis added).

The FDA recently reiterated this position. In a September 2003 publication specifically addressing nutrient content claims, the FDA stated that the NLEA “permits the use of label claims that characterize the level of a nutrient in a food (i.e., nutrient content claims) made in accordance with FDA's authorizing regulations. Nutrient content claims describe the level of a nutrient or dietary substance in the product, using terms such as *free*, *high*, and *low*, or they compare the level of a nutrient in a food to that of another food, using terms such as *more*, *reduced*, and *lite*. An accurate quantitative statement (e.g., 200 mg of sodium) that does not ‘characterize’ the nutrient level may be used to describe any amount of a nutrient present. However, a statement such as ‘only 200 mg of sodium’ characterizes the level of sodium as being low and would therefore need to conform to the criteria of an appropriate nutrient content claim or carry a disclosure statement that it does not comply with the claim.” FDA, Center for Food Safety and Applied Nutrition, Claims that Can be Made for Conventional Foods and Dietary Supplements (2003) (emphasis added) (attached hereto as 1).

In sum, the NYSRA argues that it can escape regulation simply by publishing elsewhere the same calorie values required by Health Code 81.50. If it were able to accomplish this, however, section 343-1(4)(A) of the NLEA would be meaningless; any state or local regulation that required a restaurant to disclose the amount of any nutrient would be a nutrient content claim that, the NYSRA would argue, would be preempted. Since a statute should be read to “make sense of each phrase” of the statute, the NYSRA’s attempt to equate the provision of nutritional information with the making of a nutrient content claim must be rejected. Bates, 544 U.S. at 450.

E. ASSUMING ARGUENDO THAT PURELY FACTUAL STATEMENTS ABOUT CALORIE VALUES ARE GOVERNED BY 21 U.S.C. § 343(r), THE NYSRA STILL CANNOT CLEARLY ESTABLISH THAT THE NLEA PREEMPTS HEALTH CODE 81.50.

The NLEA expressly preempts “as to any food in interstate commerce,” any state or local requirement “respecting any claim of the type described in section 343(r) of this title, made in the label or labeling of food that is not identical to the requirement of [section 343(r) of this title].” 21 U.S.C. § 343-1(a)(5). Thus, to be preempted, a state or local requirement for nutrient content claims must (a) pertain to claims made in the label or labeling of food in interstate commerce and (b) not be identical to the requirement of section 343(r).

Taking into account the analytical framework that disfavors preemption, a reading of 21 U.S.C. § 343-1(a)(5) does not compel the conclusion that Congress clearly and manifestly intended to supplant traditional state and local government regulation of menus. Bates, 544 U.S. at 449. Specifically, had Congress intended to preempt any state or local provision that regulated menus, it could have clearly said so, rather than limiting its application to claims made in the “label” or “labeling” of food. Both of these terms are defined in the FDCA. A “label” is “a display of written, printed, or graphic matter upon the immediate container of any article.” 21 U.S.C. § 321(k) (emphasis added). “Labeling” is defined to include the printed material “upon any article or any of its containers or wrappers” or “accompanying such article.”¹³ 21 U.S.C. § 321(m).

¹³ The “accompanying such article” language was explained in Kordell v. United States, 335 U.S. 345, 350 (1948), a criminal prosecution case involving drug literature that was shipped to a purchaser separately from the drug. The Court explained the “accompanying such article” provision of the definition of labeling: “One article or thing is accompanied by another when it supplements or explains it ... No physical attachment one to the other is necessary.” As to point of sale signs like menus, Kordell was distinguished in Chemical Specialties Mfrs. Ass’n v. Allenby, 958 F.2d 941 (9th Cir. 1992), an express preemption challenge based on the Federal Insecticide, Fungicide, and Rodenticide Act (“FIFRA”), 7 U.S.C. § 136v(b). Plaintiff claimed that FIFRA’s labeling definition (similar to the FDCA definition, all printed matter

While the term menu is not used at all in the NLEA, another provision of the FDCA, 21 U.S.C. § 347, does use it (as well as the term labeling). That provision sets forth detailed requirements for labeling and packaging, 21 U.S.C. § 347(b), and the sale and use in “public eating places” of colored oleomargarine. 21 U.S.C. § 347(c). Section 347(c) prohibits possession of ready-to-serve colored oleomargarine in a “public eating place” unless notice of its use is prominently displayed “or is otherwise set forth on the menu in type or lettering not smaller than that normally used to designate the serving of other food items.” Notably, the term “labeling” is used elsewhere in subsections (c) and (d), evidencing that it and the term “menu” are different.¹⁴ Since the FDCA definition of label (and labeling) does not mention the word “menu,” it is clear that Congress did not intend that 21 U.S.C. § 343-1(a)(5) preempt state and local requirements respecting claims made on menus.¹⁵

“accompanying the pesticide ... at any time”) preempted California’s Proposition 65, which allowed various methods to provide warnings for products covered by FIFRA, including point of sale signs. The Court, following New York State Pesticide Coalition, Inc. v. Jorling, 874 F.2d 115 (2nd Cir. 1989), held that such point of sale signs did not constitute labeling, rejecting plaintiff’s argument that “point of sale signs constitute labeling because they are written materials that accompany the pesticide at the point of sale.” 958 F.2d at 946.

¹⁴ Since menus are not included in the definition of labels or labeling, and 21 U.S.C. § 343 governs only labels and labeling, the FDA has no authority to regulate menus. See La. Public Service Commission v. FCC, 476 U.S. 355, 374 (1986). (“a federal agency may pre-empt state law only when and if it is acting within the scope of its congressionally delegated authority”). See also New York v. FERC, 535 U.S. 1, 18 (2002) (in determining whether a federal agency’s jurisdiction preempts state regulations, the Court should “be certain that Congress has conferred authority on the agency” to act as it did).

¹⁵ The Court’s decision in Public Citizen, Inc. v. Shalala, 932 F. Supp. 13 (D.D.C. 1996) is not dispositive. There plaintiff successfully challenged the FDA’s decision to exempt restaurant menus from its food labeling requirements. Although the FDA conceded in that case that menus constituted labeling, there are no references in either the opinion or the FDA’s discussion in its rule-making relating to the FDA exemption that specifically interprets the language of sections 321(k) and 321(m). See 58 Fed. Reg. 33055 (June 15, 1993) & 61 Fed. Reg. 40320 (Aug. 2, 1996).

Moreover, even if menus are considered labeling, Congress did not intend to foreclose all state and local regulation of nutrient content claims. In Bates, the Court considered a preemption argument based on FIFRA, and noted that Congress would have preempted “all state requirements concerning labeling” had it stated: “Such State shall not impose or continue in effect any requirements for labeling or packaging.” 544 U.S. at 448-49 (emphasis in original). Similarly, here the NLEA only preempts requirements that are “not identical to the requirement of [21 U.S.C. § 343(r)].” 21 U.S.C. § 343-1(a).¹⁶

Section 343(r) requires that a claim in the label or labeling of food “may be made only if the characterization of the level made in the claim uses terms that are defined in [FDA] regulations.” 21 U.S.C. § 343(r)(2)(A)(i). In plain English, the statute provides that, if a restaurant makes a nutrient content claim, it may only do so using language proscribed by the FDA. The legislative history supports this conclusion. For instance, Senator Metzenbaum noted that “the bill does not preempt any State nutrition labeling requirements for restaurants.” 136 Cong. Rec. S16607, 16608 (Oct. 24, 1990) (statement of Sen. Metzenbaum). Senator Metzenbaum also noted that to “the extent that a consistent format and content is used, consumers will be able to make greatest use of the nutrition information.” Id. And Senator Mitchell noted that the bill requires “uniform nutritional labeling”¹⁷ while also “preserving State

¹⁶ The Bates Court also held that since Congress added additional language to the FIFRA preemption provision (“in addition to or different from”) it was “evidence of its intent to draw a distinction between state labeling requirements that are pre-empted and those that are not.” Bates, 544 U.S. at 449. The same reasoning applies here; the fact that Congress added additional language to the NLEA preemption provision (“that is not identical to”) indicates that Congress did not intend to completely preempt all State legal provisions relating to restaurant menus.

¹⁷ Similarly, the FDA noted the need for uniformity in nutrient content claims: “Without clear definitions of the terms that describe the levels of these nutrients in food, manufacturers could use a term like ‘high in fiber’ on products that vary widely in fiber content. ... To ensure that consumers are not misled and are given reliable information, Congress found, and FDA agrees, that is appropriate for the agency to establish specific definitions to standardize the terms used by

regulatory authority where it is appropriate.” 136 Cong Rec S16607, 16609 (Oct. 24, 1990) (statement of Sen. Mitchell).

Health Code 81.50 does not require restaurants to use terms that are different than those defined by the FDA. It simply requires they put information on menus where it can be used by consumers. There is nothing in section 343(r) dictating where claims can or cannot be made. Cf., e.g., 21 U.S.C. § 343(q)(4)(D)(ii) (authorizing the FDA to require that nutritional information be provided in a single location in an area where raw fish and agricultural commodities are sold). Accordingly, Health Code 81.50 does not conflict with the requirements of section 343(r) and it would not be preempted by section 343-1(a)(5) were this Court to find that NYSRA restaurants were making nutrient content claims.

The NYSRA cites 21 C.F.R. § 101.10, which gives restaurants making nutrient content claims options to use when providing the information upon which their claims are based. A regulation, however, cannot have preemptive effect when it is enacted by an agency without statutory authority. Fidelity Fed. Sav. & Loan Ass’n v. de la Cuesta, 458 U.S. 141, 154 (1982) (citing United States v. Shimer, 367 U.S. 374, 381-82 (1961)). While section 343(r) authorizes the FDA to define terms that can be used to characterize the levels of in foods, 21 U.S.C. § 343(r)(2)(A)(i), and propose regulations to enable it to review and act promptly on certain petitions, 21 U.S.C. § 343(r)(7), it does not authorize the FDA to regulate where restaurants should make available the information upon which their claims are made. Cf. 21 U.S.C. § 343(q)(3) (authorizing the FDA to enact regulations permitting certain nutritional information to be displayed where food is offered for sale) & 21 U.S.C. § 343(q)(4)(D)(iii) (authorizing the

manufacturers to describe the nutrient content of foods.” Food Labeling, 56 Fed. Reg. 60421 (Nov. 27, 1991).

Secretary to enact regulations permitting certain nutritional information to be made “available in brochure, notebook or leaflet form, or by posting a sign disclosing the information”).

Finally, even if 21 C.F.R. § 101.10 was authorized, Health Code 81.50 is not affirmatively different from it. The NLEA only preempts state and local governments from establishing requirements that are not “identical” to 21 U.S.C. § 343(r), which the FDA indicates means not affirmatively different.¹⁸ Health Code 81.50 is not preempted since it does not mandate restaurants to do anything different from what they are permitted to do under 21 C.F.R. § 101.10.¹⁹ (Health Code 81.50 obviously does not preclude NYSRA restaurants from providing additional nutritional information on the menu or elsewhere.) Moreover, the Health Code 81.50 calorie posting requirement is consistent with the primary purpose of the NLEA, namely, to effectively inform consumers about the foods that they eat. See 136 Cong. Rec. S16607, 16608

¹⁸ The FDA explained the scope of NLEA preemption as only those “State requirements ... that are affirmatively different on matters that are covered by section 403A [§ 343-1] of the act.” State Petitions Requesting Exemption from Preemption, 58 Fed. Reg. 2462, 2462 (Jan. 6, 1993) (emphasis added)).

¹⁹ The NYSRA contends that the preemption provision, 21 U.S.C. § 343-1(a)(5), applies to both “content” (i.e. the manner in which the number of calories is calculated) and “presentation” (i.e. the manner in which the number of calories is conveyed). NYSRA Br. at 16. While the presentation of the number of calories and other nutrients on packaged food is strictly regulated by the NLEA, the presentation of nutrient content claims for restaurant food is governed by section 101.10, which gives restaurants various options in providing this information. Essentially, section 101.10 sets a minimum requirement, a floor, and merely mandates restaurants to provide such information in some undefined manner. Fundamentally, the NYSRA contends that Health Code 81.50 is preempted since it mandates the use of one permissible option under section 101.10. NYSRA Br. at 16. Besides implementing provisions that mirror section 101.10 (which would be an unnecessary exercise), the NYSRA argument essentially stands for the proposition that the States have no authority to regulate menus of restaurants within their borders. Given the States historic police power to “protect consumers by regulating foods produced and/or marketed within their borders,” Grocery Mfrs. of America, 755 F.2d at 1003, this argument should be rejected. Moreover, such an interpretation would be inconsistent with the statutory interpretation principles recently reiterated in Bates, 544 U.S. at 448-49, since Congress certainly could have (but did not) explicitly state that all state and local requirements relating to labeling were preempted. See also supra 12-13.

(Oct. 24, 1990) (Senator Metzenbaum: “By providing the public with better nutrition information, this bill makes a major step forward in enabling consumers to select foods to protect and improve their health.”).

In sum, an analysis of section 343(r), its preemption provision and its legislative history fails to clearly indicate that Congress intended to preempt traditional state and local authority over restaurants. See Bates, 544 U.S. at 449. Cf. Florida Lime & Avocado Growers, Inc. v. Paul, 373 U.S. 132, 142 (1963) (in implied preemption case, Court notes that “federal regulation of a field of commerce should not be deemed preemptive of state regulatory power in the absence of persuasive reasons – either that the nature of the regulated subject matter permits no other conclusion, or that the Congress has unmistakably so ordained” (citations omitted)). Having failed to rebut the presumption against preemption, the NYSRA’s request for declaratory relief must be denied even if restaurants are deemed to have made nutrient content claims merely by identifying the number of calories contained in their food.

**II. NYSRA'S REQUEST FOR PRELIMINARY
INJUNCTIVE RELIEF ON ITS FIRST
AMENDMENT CLAIM SHOULD BE
DENIED SINCE IT HAS NOT
DEMONSTRATED A LIKELIHOOD OF
SUCCESS ON THIS CLAIM.**

Health Code 81.50 merely specifies one point in a commercial transaction, the point of purchase, where restaurants must disclose factual information that NYSRA restaurants already disclose in other formats.

**A. THE PROPER ANALYTICAL FRAMEWORK FOR JUDGING COMPELLED
FACTUAL DISCLOSURE IS THE ZAUDERER REASONABLENESS
STANDARD.**

In Zauderer v. Office of Disciplinary Counsel, 471 U.S. 626 (1985), the Supreme Court developed an analytical framework where a governmental regulation “compels” truthful disclosure of purely factual, non-opinion, non-political, non-ideological information to the consumer. At issue in Zauderer was a state attorney disciplinary rule providing that an attorney who advertised his availability to bring Dalkon Shield personal injury cases on a contingency basis must make a fuller disclosure about litigation costs if she did not prevail on her claim. 471 U.S. at 630. The advertisement stated that if the litigant lost the case, no fees, meaning attorney fees, would be owed. Id. at 631. But the advertisements were deemed deceptive because they omitted the fact that the “significant litigation costs” of bringing the lawsuit would be owed. Id. at 633.

In holding that the disciplinary rule did not violate the First Amendment, the Court specifically drew a distinction between regulations that compelled disclosure and those that restricted speech. The Court stated:

Ohio has not attempted to prevent attorneys from conveying information to the public; it has only required them to provide

somewhat more information than they might otherwise be inclined to present.

471 U.S. at 651. The Court specifically rejected the argument that the disclosure requirement, in order to be constitutional, had to be "the least restrictive means" or "not more extensive than necessary" to serve the governmental interest, the standard of scrutiny set forth in Central Hudson Gas & Electric Corp. v. Public Service Commission of New York, 447 U.S. 557 (1980). The Court in Zauderer held that commercial speech could be compelled so "long as disclosure requirements are reasonably related to the State's interest in preventing deception of consumers." 471 U.S. at 651 (emphasis added). The Court explained that this very lenient standard was appropriate "[b]ecause the extension of First Amendment protection to commercial speech is justified principally by the value to consumers of the information such speech provides," and the speaker's "constitutionally protected interest in not providing any particular factual information in his advertising is minimal." Id.

Following Zauderer, the Second Circuit, in Nat'l Elec. Mfr. Assoc. v. Sorrell, 272 F.3d 104 (2d Cir. 2001), cert. denied, 536 U.S. 905 (2002), applied the reasonableness standard to uphold a regulation requiring warnings on products containing mercury. The Court held that "mandated disclosure of accurate, factual, commercial information does not offend the core First Amendment values of promoting efficient exchange of information or protecting individual liberty interest." Id. at 113. The Court reasoned that "such disclosure furthers, rather than hinders, the First Amendment goal of the discovery of truth and contributes to the efficiency of the "marketplace of ideas." Id. at 114.

Thus, the Second Circuit concluded:

In sum, mandating that commercial actors disclose commercial information ordinarily does not offend the important utilitarian and individual liberty interests that lie at the heart of the First Amendment. The Amendment is satisfied, therefore, by a rational

connection between the purpose of a commercial disclosure requirement and the means employed to realize that purpose.

Id. at 115. See also European Connection & Tours, Inc. v. Gonzales, 480 F. Supp. 2d 1355 (N.D. Ga. 2007) (government "disclosure requirements are properly analyzed under Zauderer and must be upheld if there is a reasonable relationship to a legitimate governmental interest").

NYSRA attempts to distinguish Zauderer and Sorrell from this case in a footnote. NYSRA Br., at 23, fn.6. Citing United States v. United Foods, Inc., 533 U.S. 405, 416 (2001), it argues that Zauderer should only be applied to regulations that are designed to prevent deception. NYSRA Br., at 3, fn.6. United Foods, however, was a subsidized speech claim involving a requirement that fresh mushroom handlers pay assessments to fund advertisements promoting the mushroom sales of other handlers. There, the Court held that the government could not impose assessments to pay for a certain viewpoint. Although the Court noted that the government did not argue that assessments were necessary to prevent consumers from being misled, 533 U.S. at 416, the Court did not limit the application of Zauderer to disclosures designed to prevent deception.

The lenient standard of review set forth in Zauderer is to be applied whenever a regulation compels the disclosure of uncontroverted facts because it recognizes the "minimal" interest the speaker has in not disclosing such information. It is to be applied, regardless of why the disclosure of uncontroverted facts is being mandated. Thus, NYSRA's argument that Zauderer is not applicable because Health Code 81.50 was not intended to prevent deception is meritless. See Sorrell, 272 F.3d at 115 (compelled disclosure valid pursuant to Zauderer even though the issue was not the prevention of consumer confusion or deception per se, but rather to better inform consumers about the products they were purchasing); see also, Pharmaceutical Care Mgmt. Ass'n v. Rowe, 429 F.3d 294, 310 fn.8 (1st Cir. 2005), cert. denied, 126 S. Ct. 2360

(2006) (Zauderer's applicability is not limited only to speech preventing deception) (both cases decided after United Foods).

In any event, the absence of calorie information can mislead consumers about the number of calories they are consuming. As discussed in Dr. Frieden's Declaration, ¶¶ 24, 29, 30, consumers are not generally aware of calorie counts. A study indicated that the more calories there are in a meal, the more people underestimate the amount they believe they eat. Frieden Decl. ¶ 27. In its Statement of Basis and Purpose in the Notice of Adoption for section 81.50, the Board of Health noted that "studies found that 9 out of 10 people underestimated the calorie content of less-healthy items by an average of more than 600 calories." Frieden Decl. ¶ 32 & Ex. 10.

NYSRA also contends that calorie counts are not "purely factual and non-controversial." NYSRA Br., at 23, n. 6. Citing Riley v. Nat'l Fed'n of the Blind, 487 U.S. 781, 796 (1988), NYSRA argues that there is no distinction between compelled statements of opinion and fact, and that "either form of compulsion' burdens protected speech." NYSRA Br., at 21. In Riley, the factual information North Carolina sought to have disclosed by charitable fundraisers was inextricably intertwined with the core protected speech of the charities for which the funds were being raised. Most significantly, the Court in that case noted that regulation of charitable solicitation must "be undertaken with due regard" because it "is characteristically intertwined with informative and perhaps persuasive speech . . . , and for the reality that without solicitation the flow of such information and advocacy would likely cease." 487 U.S. at 796. Thus, NYSRA's reliance on Riley is completely misplaced because the disclosure of a calorie count is not intertwined with protected speech.

Equally without merit is NYSRA's argument that this Court should apply a heightened scrutiny test because its members have been compelled to express not just facts, but a message with which its members disagreed. Specifically, NYSRA argues that "the Regulation forces restaurants to use their most important tool for communicating with their customers to voice a point of view with which they disagree, namely that calories are the only nutritional criterion that patrons need to consider when making food selections." NYSRA Br., at 21. In making this argument, plaintiff conveniently ignores the fact that its members are free to post additional information and even a disclaimer if they so choose. See Frieden Decl. ¶ 28. See also Meese v. Keene, 481 U.S. 465, 481 (1987) (in upholding an act which required labeling on movies made by foreign governments as "political propaganda," the Court noted that "Congress simply required the disseminators of such material to make additional disclosures that would better enable the public to evaluate the import of the propaganda. ... Disseminators of propaganda may go beyond the disclosures required by statute and add any further information they think germane to the public's viewing of the materials").

Further, there is no "message" involved here, only factual information which plaintiff's members have already chosen to publicly disclose elsewhere. Thus, the compelled speech cases cited by NYSRA, where the government has impermissibly required the speakers to promote messages with which they disagree are completely inapposite.²⁰

Also baseless is NYSRA's argument that the posting requirements "will make menu boards confusing and difficult for consumers to read, directly interfering with the ability of

²⁰ See, e.g., West Virginia Board of Education v. Barnette, 319 U.S. 624 (1943) (requiring school children to cite the Pledge to Allegiance); Wooley v. Maynard, 430 U.S. 705 (1977) (requiring cars to bear license plates with state's motto: "Live Free or Die"); Pacific Gas & Electric Co. v. Public Utilities Commission of California, 475 U.S. 1 (1986) (a requirement that a utility company include in its billing envelopes messages prepared by a consumer organization).

such restaurants to communicate with their customers.” NYSRA Br., at 7. Menu Board clutter is a matter of design, and not a question of burdening protected speech. See Declaration of Bruce Kruger (discussing the redesign of a menu board for Dunkin’ Donuts in order to comply with Health Code 81.50 requirements and providing an example of how it could be easily and legibly done).

In sum, Health Code 81.50 should be analyzed under the reasonableness standard set forth in Zauderer and applied in Sorrell because it mandates disclosure of facts in a purely commercial context.

B. HEALTH CODE 81.50 IS RATIONALLY RELATED TO THE CITY'S LEGITIMATE INTEREST IN PROTECTING PUBLIC HEALTH.

As more fully discussed in Dr. Frieden’s declaration, New York City is facing an obesity epidemic and the health consequences associated with obesity. Heart disease, stroke, cancer and diabetes are four of the five leading causes of death in New York City in 2005 with 40,771 victims (71% of all deaths). These conditions are significantly more prevalent among persons who are obese. Frieden Decl. ¶ 6. More than 9%, or half a million New Yorkers have diagnosed diabetes, and another 200,000 have it and do not know it; this number has increased over the past decade. About 22%, or 1.2 million New Yorkers, have higher than normal fasting blood sugars that, while not in the range of diabetes, put them at high risk for developing diabetes. Among New Yorkers who have diabetes, 80% are overweight or obese. Both diabetes and obesity have increased rapidly in New York City, as they have nationally. Frieden Decl. ¶¶ 9-10.

Health Code 81.50's requirement that calories be posted at the point of sale is reasonably related to the City's substantial interest in curbing the obesity epidemic. First, an estimated one third of daily caloric intake for all Americans comes from foods purchased outside

of the home. Frieden Decl. ¶ 4. Although the NLEA, 21 U.S.C. § 343(q), has made nutrition information available to consumers on packaged foods purchased in retail stores, this requirement does not apply to restaurants.

Calories are increasingly recognized as the single most important element of nutrition information to address the obesity epidemic. As explained in Dr. Frieden's Declaration, calorie content is the metric for energy intake and caloric intake is the most important element of weight control. Weight gain results from more energy consumed (as measured in calories) than expended through physical activity. While there are many other dietary variables of importance to consumers (e.g., fat, sodium), the basic relationship of calories to energy balance and weight control is fundamental. Frieden Decl. ¶¶ 14, 23.

In fact, the FDA's Obesity Working Group ("OWG") concluded in its 2005 work with a report entitled "Calories Count" that "weight control is primarily a function of balance of the calories eaten and calories expended on physical and metabolic activity." Frieden Decl. ¶ 19, Ex. 5.

Additionally, the final report of the FDA-commissioned Keystone Forum on Away-From-Home Foods recommends that food service establishments "provide consumers with calorie information in a standard format that is easily accessible and easy to use." Frieden Decl. ¶ 25, Ex. 8. Health Code 81.50, which requires putting calorie information next to menu items, is consistent with this recommendation.

NYSRA argues that calorie information is useless if consumers are unaware of their daily recommended calorie intake. However, even if consumers do not know their total recommended daily calorie intake, they can compare calorie levels of different menu items, and make more informed decisions. Frieden Decl. ¶ 21. This is particularly true because consumers

are generally familiar with calories from nutrition labels on foods they purchase for consumption at home. Three-quarters of American adults report using food labels, and about half (48%) report that nutrition information on food labels has caused them to change their food purchasing habits. The calorie section is the most frequently consulted part of the Nutrition Facts panel on packaged foods, with 73% of consumers reporting that they look at it. See Frieden Decl. ¶ 17

Having calorie information readily apparent at the point of sale is the most effective way to get this information to consumers who are eating outside their homes. Currently, restaurants that would be covered under Health Code 81.50 do not effectively transmit calorie information. These current voluntary attempts by some restaurants fail because the information is usually not displayed where consumers are making their choices and purchases, such as when a restaurant's nutrition information is available on the internet. While such information may also be available in brochures, on placemats covered with food items, or on food wrappers, where the information is hard to find or difficult to read and only accessible after the purchase is made. Thus the information as provided has little impact on choice.

In May and June of this year, DOH randomly surveyed 274 of the restaurants affected by this rule. Less than 8% of customers reported seeing calorie information in the restaurant where they had eaten. The percentage was particularly low (< 5%) among those restaurants (McDonald's, Dunkin' Donuts, Burger King, and Yum Brands locations) who have submitted declarations in support of NYSRA's complaint, and whose declarations claim that they provide extensive nutrition information to customers. Frieden Decl. ¶¶ 29, 30.

A study found that when calorie information is readily available, high-calorie menu items are chosen one-third less often. National polls indicate that at least 60% of

respondents would like calories to be listed on menus or menu boards in chain restaurants. Frieden Decl. ¶¶ 26, 32, 33-34, Ex. 7.

In fact, a report commissioned by the FDA has concluded that "restaurants should provide consumers with calorie information in a standard format that is easily accessible and easy to use," so that consumers are able to view the calorie information "when standing at a counter, while reviewing a menu board, in a car when reading a drive-through menu, or when sitting down at a table reviewing a menu." Frieden Decl. ¶ 25.

NYSRA's argument that Health Code 81.50 will have no impact on curbing obesity because it applies to only 10% of the City's restaurants (NYSRA Br., at 27) is meritless. First, this percentage is not insignificant; when market share is taken into consideration, these restaurants constitute approximately 40% of restaurant visits nationwide. Even using plaintiff's 10% figure in New York City, more than one hundred million, and possibly more than 400 million, meals would be affected by this regulation each year. See Frieden Decl. ¶¶ 53, 49-53. Moreover, the Court in Zauderer rejected this type of "under inclusive" argument and stated: "as a general matter, governments are entitled to attack problems piecemeal, save where their policies implicate rights so fundamental that strict scrutiny must be applied." 471 U.S. at 651, n.14.

NYSRA argues that there is no empirical data that posting calorie counts on menu boards will affect consumer choice in the desired direction. NYSRA Br., at 27-28. Health Code 81.50 is supported by the wealth of studies set forth in Dr. Frieden's Declaration. Even if that were not the case, there is no requirement that Health Code 81.50 be supported by empirical data with undisputed scientific proof. In Lorillard Tobacco Co. v. Reilly, 533 U.S. 525, 555 (2001), the Court, in applying the third Central Hudson factor, stated:

We do not, however, require that “empirical data come . . . accompanied by a surfeit of background information . . . We have permitted litigants to justify speech restrictions by reference to studies and anecdotes pertaining to different locales altogether, or even, in a case applying strict scrutiny, to justify restrictions based solely on history, consensus, and ‘simple common sense.’”

Certainly, if such proof is not necessary under Central Hudson, it is not required under the more lenient standard set forth in Zauderer, which is applicable here.

Contrary to NYSRA’s suggestions (NYSRA Br., at 5-6), there was an extensive comment and review process undertaken prior to the adoption of Health Code 81.50. After giving notice in September 2006 of its intention to amend the Health Code, the Board of Health received approximately 2,200 written and oral comments, including submissions by NYSRA’s parent organization, the National Restaurant Association. As set forth in Dr. Frieden’s Declaration, ¶ 54, supportive statements were provided by numerous medical associations, hospitals, public interest groups and medical schools. Copies of exemplary statements are attached to Dr. Frieden’s declaration as Exhibit 11.

Based on the above and as more fully explained in Dr. Frieden’s Declaration, Health Code 81.50’s requirement that calorie information be provided at the point of sale is reasonably related to the City’s legitimate and substantial interest in reducing inaccurate perceptions of consumers and curbing obesity and the health consequences associated with it. Thus, Health Code 81.50 does not violate the First Amendment. See Zauderer; Sorrell.²¹

²¹ Health Code 81.50 would also be constitutionally permissible under the standards set forth in Central Hudson. There is no dispute as to the first two prongs. As stated earlier, in demonstrating the third prong of Central Hudson, whether the regulation directly advances the governmental interest asserted, defendants can rely on “studies,” “consensus” and “simple common sense.” Clearly, the City has met that burden: increased knowledge about calories is associated with reduced consumption, reduced obesity, and reduced diabetes. With respect to the fourth prong, whether the restriction is not more extensive than necessary to serve the government’s interests, the City must demonstrate “a reasonable fit” between the City’s interests and the means chosen to accomplish those goals. The “fit need not be ‘perfect,’ but must be

C. HEALTH CODE 81.50 DOES NOT UNLAWFULLY CHILL PROTECTED SPEECH.

NYSRA also argues that Health Code 81.50 chills commercial speech because some of its members have removed nutrition information which had been previously available to avoid its requirements. This argument, too, is without merit.

The Supreme Court has stated that "[c]ommercial speech, because of its importance to business profits, and because it is carefully calculated, is also less likely than other forms of speech to be inhibited by proper regulation." Friedman v. Rogers, 440 U.S. 1, 10 (1979); see also, Kraft, Inc. v. Federal Trade Commission, 970 F.2d 311, 321 (7th Cir. 1992), cert. denied, 507 U.S. 909 (1993) ("commercial speech is generally considered less susceptible to the chilling effect of regulation than other, more traditionally recognized forms of speech, such as political discourse").

Thus, in Zauderer, the Court stated:

We recognize that unjustified or unduly burdensome disclosure requirements might offend the First Amendment by chilling protected commercial speech. But we hold that an advertiser's rights are adequately protected as long as disclosure requirements are reasonably related to the State's interest in preventing deception of consumers.

471 U.S. at 651. See also, Beeman & Pharmacy Services, Inc. v. Anthem Prescription Management, Inc., 2007 U.S. Dist. LEXIS 39779, *36 (C.D. Cal. May 4, 2007) ("When the affected or chilled expression is commercial speech, the Court applies a form of rational basis review.").

reasonable. Bd of Trustees v. Fox, 492 U.S. 469, 480 (1969). As NYSRA acknowledged, the menu boards are "the most important tool for communicating with their customers." NYSRA Br., at 21. Clearly, posting the calories there would be the most effective way of getting this information to the consumer.

Since Health Code 81.50 is reasonably related to the City's legitimate goal of reducing consumer misperception and curbing obesity, NYSRA's chilling argument must be rejected. Even if the rational basis of Health Code 81.50 were not dispositive of NYSRA's chilling claim, its argument must nevertheless be rejected.

NYSRA has not demonstrated that the disclosure required by Health Code 81.50 is so unduly burdensome that it would chill protected speech. First, other disclosure requirements that are triggered by voluntary disclosure have not been declared unconstitutional as chilling protected speech, i.e., the requirements set forth in NLEA section 343(r) for restaurants that have made nutrient content and health claims. Moreover, there is no burden placed on establishments to disclose any information that they have not already compiled and released to the public.

Additionally, Health Code 81.50 allows NYSRA restaurants, through an alternative design process, to exercise flexibility in how they display calorie information at the point of purchase, subject to the DOH's prior approval and to meeting the "equal prominence" standard specified in Health Code 81.50. Contrary to NYSRA's argument, DOH has preliminarily approved some alternative means for making calorie information available. See Frieden Decl. ¶¶ 59-60.²²

Finally, a restaurant can account for individual customization of an item by posting calories for the standard preparation of the item, along with a disclaimer that calorie amounts may differ due to individual preferences. Many restaurants already provide such

²² A determination by DOH denying a request for approval of an alternate design would be subject to judicial review pursuant to Article 78 of the New York State Civil Practice Law and Rules.

disclaimers on their publicly available calorie information. Alternatively for certain products, a range of calories can be provided. See Frieden Decl. ¶ 66.

Based on the above, Health Code 81.50, which is rationally related to a legitimate governmental interest, does not "offend the First Amendment by chilling protected commercial speech." Zauderer, 471 U.S. at 651.

In sum, NYSRA's motion for preliminary injunctive relief on its First Amendment claim should be denied because NYSRA has failed to demonstrate that it has a likelihood of success on the merits of its First Amendment claim.

CONCLUSION

For the reasons set forth above, the Court should deny NYSRA's motion for declaratory relief on its preemption claim and for preliminary injunctive relief on its First Amendment claim.

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CFSAN/Office of Nutritional Products, Labeling, and Dietary Supplements
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Claims That Can Be Made for Conventional Foods and Dietary Supplements

Claims that can be used on food and dietary supplement labels fall into three categories: health claims, nutrient content claims, and structure/function claims. The responsibility for ensuring the validity of these claims rests with the manufacturer, FDA, or, in the case of advertising, with the Federal Trade Commission.

I. Health Claims

Health claims describe a relationship between a food, food component, or dietary supplement ingredient, and reducing risk of a disease or health-related condition. There are three ways by which FDA exercises its oversight in determining which health claims may be used on a label or in labeling for a food or dietary supplement: 1) the 1990 Nutrition Labeling and Education Act (NLEA) provides for FDA to issue regulations authorizing health claims for foods and dietary supplements after FDA's careful review of the scientific evidence submitted in health claim petitions; 2) the 1997 Food and Drug Administration Modernization Act (FDAMA) provides for health claims based on an authoritative statement of a scientific body of the U.S. government or the National Academy of Sciences; such claims may be used after submission of a health claim notification to FDA; and 3) the 2003 FDA *Consumer Health Information for Better Nutrition Initiative* provides for qualified health claims where the quality and strength of the scientific evidence falls below that required for FDA to issue an authorizing regulation. Such health claims must be qualified to assure accuracy and non-misleading presentation to consumers. The differences between these three methods of oversight for health claims are summarized below. Appendix C of *The Food Labeling Guide* contains a summary of those health claims that have been approved for use on food and dietary supplement labels:
<http://www.cfsan.fda.gov/~dms/flg-6c.html>.

A "health claim" by definition has two essential components: (1) a substance (whether a food, food component, or dietary ingredient) and (2) a disease or health-related condition. A statement lacking either one of these components does not meet the regulatory definition of a health claim. For example, statements that address a role of dietary patterns or of general categories of foods (e.g., fruits and vegetables) in health are considered to be dietary guidance rather than health claims, provided that the context of the statement does not suggest that a specific substance is the subject. Dietary guidance statements used on food labels must be truthful and non-misleading. Statements that address a role of a specific substance in maintaining normal healthy structures or functions of the body are considered to be structure/function claims. Structure/function claims may not explicitly or implicitly link the relationship to a disease or health related condition. Unlike health claims, dietary guidance statements and structure/function claims are not subject to FDA review and authorization. There are some regulatory requirements associated with the use of structure/function claims; see <http://www.cfsan.fda.gov/~dms/labstruc.html>.

NLEA Authorized Health Claims. The Nutrition Labeling and Education Act (NLEA) of 1990, the Dietary Supplement Act of 1992, and the Dietary Supplement Health and Education Act of 1994 (DSHEA), provide for health claims used on labels that characterize a relationship between a food, a food component, dietary ingredient, or dietary supplement and risk of a disease (for example, "diets high in calcium may reduce the

risk of osteoporosis"), provided the claims meet certain criteria and are authorized by an FDA regulation. FDA authorizes these types of health claims based on an extensive review of the scientific literature, generally as a result of the submission of a health claim petition, using the significant scientific agreement standard to determine that the nutrient/disease relationship is well established. For an explanation of the significant scientific agreement standard, see: <http://www.cfsan.fda.gov/~dms/ssaguide.html>.

Health Claims Based on Authoritative Statements. The Food and Drug Administration Modernization Act of 1997 (FDAMA) provides a second way for the use of a health claim on foods to be authorized. FDAMA allows certain health claims to be made as a result of a successful notification to FDA of a health claim based on an "authoritative statement" from a scientific body of the U.S. Government or the National Academy of Sciences. FDA has prepared a guide on how a firm can make use of authoritative statement-based health claims. This guide can be found at: <http://www.cfsan.fda.gov/~dms/hclmguid.html>. FDAMA does not include dietary supplements in the provisions for health claims based on authoritative statements. Consequently, this method of oversight for health claims cannot be used for dietary supplements at this time. Examples of health claims based on authoritative statements may also be found at: <http://www.cfsan.fda.gov/~dms/flg-6c.html>.

Qualified Health Claims. FDA's 2003 *Consumer Health Information for Better Nutrition Initiative* provides for the use of qualified health claims when there is emerging evidence for a relationship between a food, food component, or dietary supplement and reduced risk of a disease or health-related condition. In this case, the evidence is not well enough established to meet the significant scientific agreement standard required for FDA to issue an authorizing regulation. Qualifying language is included as part of the claim to indicate that the evidence supporting the claim is limited. Both conventional foods and dietary supplements may use qualified health claims. FDA uses its enforcement discretion for qualified health claims after evaluating and ranking the quality and strength of the totality of the scientific evidence. Although FDA's "enforcement discretion" letters are issued to the petitioner requesting the qualified health claim, the qualified claims are available for use on any food or dietary supplement product meeting the enforcement discretion conditions specified in the letter. FDA has prepared a guide on interim procedures for qualified health claims and on the ranking of the strength of evidence supporting a qualified claim, see: <http://www.cfsan.fda.gov/~dms/hclmgui3.html>. Qualified health claim petitions that are submitted to FDA will be available for public review and comment. A listing of petitions open for public comment is at the FDA Dockets Management website. A summary of the qualified health claims authorized by FDA may be found at: <http://www.cfsan.fda.gov/~dms/qhc-sum.html>. For more information on Qualified Health Claims, see <http://www.cfsan.fda.gov/~dms/lab-qhc.html>.

II. Nutrient Content Claims

The Nutrition Labeling and Education Act of 1990 (NLEA) permits the use of label claims that characterize the level of a nutrient in a food (i.e., nutrient content claims) made in accordance with FDA's authorizing regulations. Nutrient content claims describe the level of a nutrient or dietary substance in the product, using terms such as *free*, *high*, and *low*, or they compare the level of a nutrient in a food to that of another food, using terms such as *more*, *reduced*, and *lite*. An accurate quantitative statement (e.g., 200 mg of sodium) that does not "characterize" the nutrient level may be used to describe any amount of a nutrient present. However, a statement such as "only 200 mg of sodium" characterizes the level of sodium as being low and would therefore need to conform to the criteria of an appropriate nutrient content claim or carry a disclosure statement that it does not comply with the claim. Most nutrient content claim regulations apply only to those nutrients or dietary substances that have an established daily value: <http://www.cfsan.fda.gov/~dms/flg-7a.html>. The requirements that govern the use of nutrient content claims help ensure that descriptive terms, such as *high* or *low*, are used consistently for all types of food products and are thus meaningful to consumers. *Healthy* has been defined by a regulation as an implied nutrient content claim that characterizes a food that has "healthy" levels of total fat, saturated fat, cholesterol and sodium. Percentage claims for dietary supplements are another category of nutrient content claims. These claims are used to describe a percentage level of a dietary ingredient for which there is no established Daily Value. Examples include simple percentage statements such as "40% omega-3 fatty acids, 10 mg per capsule," and comparative percentage claims, e.g.,

"twice the omega-3 fatty acids per capsule (80 mg) as in 100 mg of menhaden oil (40 mg)." (See 21 CFR 101.13(q)(3)(ii): <http://www.cfsan.fda.gov/~lrd/cf101-13.html>.) A summary of the rules for use of nutrient content claims can be found in Chapter VI of The Food Labeling Guide: <http://www.cfsan.fda.gov/~dms/flg-toc.html>. Examples of nutrient content claims can be found in Appendices A and B of The Food Labeling Guide: <http://www.cfsan.fda.gov/~dms/flg-6a.html> and <http://www.cfsan.fda.gov/~dms/flg-6b.html>.

III. Structure/Function Claims

Structure/function claims have historically appeared on the labels of conventional foods and dietary supplements as well as drugs. However, the Dietary Supplement Health and Education Act of 1994 (DSHEA) established some special regulatory procedures for such claims for dietary supplement labels. Structure/function claims describe the role of a nutrient or dietary ingredient intended to affect normal structure or function in humans, for example, "calcium builds strong bones." In addition, they may characterize the means by which a nutrient or dietary ingredient acts to maintain such structure or function, for example, "fiber maintains bowel regularity," or "antioxidants maintain cell integrity," or they may describe general well-being from consumption of a nutrient or dietary ingredient. Structure/function claims may also describe a benefit related to a nutrient deficiency disease (like vitamin C and scurvy), as long as the statement also tells how widespread such a disease is in the United States. The manufacturer is responsible for ensuring the accuracy and truthfulness of these claims; they are not pre-approved by FDA but must be truthful and not misleading. If a dietary supplement label includes such a claim, it must state in a "disclaimer" that FDA has not evaluated the claim. The disclaimer must also state that the dietary supplement product is not intended to "diagnose, treat, cure or prevent any disease," because only a drug can legally make such a claim. Further information regarding structure/function claims can be found in FDA's January 9, 2002 Structure/Function Claims Small Entity Compliance Guide: <http://www.cfsan.fda.gov/~dms/scfmguid.html>. Manufacturers of dietary supplements that make structure/function claims on labels or in labeling must submit a notification to FDA no later than 30 days after marketing the dietary supplement that includes the text of the structure/function claim.

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 For more recent information on Dietary Supplements
 See <http://www.cfsan.fda.gov/~dms/supplmnt.html>

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